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|--|-------------|----------------------|---------------------------------|-----------------------------|
| 10/691,859   | 10/23/2003  | Charmaine K. Harris  | 539.3113.1 (P0011285.00)        | 6734                        |
| 81390 7590 11/24/2009<br>Intellectual Property Group, MDT Patents<br>Fredrikson & Byron, P.A.<br>200 South Sixth Street, Suite 4000<br>Minneapolis, MN 55402 |             |                      |                                 |                             |
|  |             |                      | EXAMINER<br>ALTER, ALYSSA MARGO |                             |
|  |             |                      | ART UNIT<br>3762                | PAPER NUMBER                |
|  |             |                      | NOTIFICATION DATE<br>11/24/2009 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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### Office Action Summary

**Application No.**

10/691,859

**Applicant(s)**

HARRIS, CHARMAINE K.

**Examiner**

Alyssa M. Alter

**Art Unit**

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3, 4, 6-9 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 4 and 6-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1, 3, 4, 6-9 and 30-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Newly submitted claims 30-33 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions II (newly submitted claims 30-33) and I (claims 1, 3-4 and 6-9) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. The process requires the implantation and introduction of a medical lead through the "ligamentum flavum and into an epidural space" while the apparatus can be used to stimulate the spinal cord from a location other than the epidural space, i.e. external to the body. The apparatus of Invention I does not specify that the lead is suitable for implantation nor does it claim an "implantable medical lead".

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 30-33 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Response to Arguments***

Applicant's arguments filed July 14, 2009 have been fully considered but they are not persuasive.

The Applicant maintains that Putz teaches away from an orientation marker that is displaced from an electrode array. However, the examiner maintains that Putz does not teach away from the "radiopaque dielectric means adjacent to at least one of the contacts" (col. 3, lines 11-13) and "as in other embodiments, this indicates the positions of all contacts" (col. 3, lines 18-19). Therefore, Putz teaches the employment of orientation markers to distinguish the location of the electrodes in the electrode array.

As such, moving or relocating the orientation marker in Putz away from the electrode array would still enable Putz to determine the position of the electrodes. Therefore, Putz does not teach away from an orientation marker that is displaced from an electrode array. Furthermore, Putz would still be able to determine the locations of the electrodes when the orientation marker in the event it is displaced from the electrode array. Therefore, such a modification to Putz would render the invention of Putz satisfactory for its intended purpose, i.e. determining the locations of the electrodes.

Additionally, the Applicant argues that while Putz does not specify a particular length between the proximal edge and the electrode array, "it is evident from the disclosure of Putz that the length is significantly shorter than 40mm". However, the examiner still maintains that Putz does not close the exact length of the electrode free portion and it would be obvious to modify the length of the electrode free portion in order to provide the predictable results of ensuring proper stimulation or sensing to locations.

Therefore claims 1, 3-4 and 6-9 remain rejected under Putz as detailed below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-4 and 6-9 are rejected under 35 USC 103(a) as being unpatentable over Putz (US 4,903,702). Putz discloses a medical lead with an electrode array located on the longitudinal centerline of a generally flat paddle. The paddle has a proximal and distal end with at least one electrode exposed through a first major surface and insulated by a second major surface. Furthermore, the electrode array is displaced from the proximal end of the paddle and thus the end of the paddle lead is free from electrodes. Additionally, the medical lead also includes a radiopaque marker (depicted as 34 in figures 2-4 and 46 in figure 6) to indicate the orientation and position of the contacts located on the paddle.

Although the orientation marker is placed on the longitudinal centerline with at least one electrode, it would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the location of the radiopaque marker since it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified Putz to include an orientation marker displaced from the center line, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04). Furthermore, such a relocation of the orientation marker would still provide the predictable results of

enabling the clinician to monitor the paddle electrode during implantation, regardless of location on the paddle.

Furthermore, Putz discloses in col. 6, lines 50-55, "radiopaque dielectric markers can be in the form of separate pieces added to the flat constructions as shown, or they can be incorporated within the flexible member in other ways. For example, the flexible dielectric sheets can have radiopaque enhanced portions incorporated therein during their formation processes". Therefore, the enhanced portions of the paddle would obviously enable a location that is displaced from the centerline and the electrodes.

Additionally, as to claim 1, Putz discloses the device substantially as claim, but is silent as to the length of the electrode free portion of the paddle. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the portion to be more than at least 40 mm in order to provide the predictable results of ensuring proper stimulation or sensing to locations deep within the muscular or vasculature. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the length of the electrode free portion, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). It additionally has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (see MPEP 2144.04).

As to claim 4, Putz discloses an orientation marker and the specific location of the orientation marker and thus would necessarily enable the identification of the type of

lead model. Alternatively, although the examiner considers Putz to disclose an orientation maker to determine the model above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the lead as taught by Putz with an orientation marker coded with identification information about the lead since the availability of lead specific data would provide the predictable results of determining system compliance and manufacturing defects.

As to claims 6 and 8, Putz discloses the claimed invention except for radio-opaque material comprising platinum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07). Furthermore, such a modification from one type of radio-opaque material to a different type of radio-opaque material such as platinum, would provide the predictable results of enabling the observation of the lead post implantation and provide a conventional marker.

As to claim 9, Putz discloses the claimed invention except for transparent polyurethane material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416 (See MPEP 2144.07). Furthermore, such a modification from silicone to substantially transparent polyurethane would provide the predictable results of

maintaining biocompatible and providing the ability to observe possible defects in the lead paddle.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Primary Examiner, Art Unit 3762

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